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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S.

Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR Part 404 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301-496-7057; fax: 301-402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Multiple Antigenic Peptide Assays for Detection of HIV and SIV Type Retroviruses

Description of Technology: CDC scientists have developed multiple antigenic peptide immunoassays for the detection of human immunodeficiency virus (HIV) and/or simian immunodeficiency virus (SIV). HIV can be subdivided into two major types, HIV-1 and HIV-2, both of which are believed to have originated as result of zoonotic transmission. Humans are increasingly exposed to many different SIVs by wild primates. For example, human exposure to SIVs frequently occurs as a consequence of the bush meat hunting and butchering trade in Africa. Human exposure to SIVs may lead, or may have already led, to transmission of SIVs with potential for new virus induced immunodeficiency epidemics. Unfortunately, new cases of zoonotic virus transmission may go undetected because of the lack of SIV-specific tests. Thus, there is the potential to compromise the safety of the blood donor supply system and seed a new HIV-like epidemic. This invention addresses these problems by providing a way to test all primates for the many divergent lentivirus strains to identify primary infections and prevent secondary transmission.

Potential Commercial Applications:

- Detection and differentiation of HIV-1, HIV-2 and SIVs
- HIV/SIV surveillance
- SIV/HIV/AIDS research
- Sero-monitoring of potential zoonotic transmissions
- Blood-donation supply assurance tool

Competitive Advantages:

- Fills an unmet need for SIV-specific tests
- Sensitive and specific
- Easily adapted to kit/array format
- Research indicates greater sensitivity than standard HIV enzyme immunoassays

(EIAs) for detecting SIV infections

Development Stage: In vitro data available

Inventors: Marcia L. Kalish, Clement B. Ndongmo, Chou-Pong Pau, William M. Switzer, Thomas M. Folks (all of CDC)

Publication:

1. Ndongmo CB, et al. New multiple antigenic peptide-based enzyme immunoassay for detection of simian immunodeficiency virus infection in nonhuman primates and humans. J Clin Microbiol. 2004 Nov;42(11):5161-9. [PMID 15528710]
2. Kalish ML, et al. Central African hunters exposed to simian immunodeficiency virus. Emerg Infect Dis. 2005 Dec;11(12):1928-30. [PMID 16485481]

Intellectual Property: HHS Reference No. E-294-2013/0 –

- PCT Application No. PCT/US2004/011022 filed 08 Apr 2004
- US Patent No. 8,254,461 issued on 03 Sep 2013
- Various international patent applications pending or issued

Licensing Contact: Whitney Blair, J.D., M.P.H.; 301-435-4937;

whitney.blair@nih.gov

Auscultatory Training System and Telemedicine Tool with Accurate Reproduction of Physiological Sounds

Description of Technology: This CDC developed auscultatory training apparatus includes a database of prerecorded physiological sounds (e.g., lung, bowel, or heart sounds) stored on a computer for playback. Current teaching tools, which utilize previously recorded sounds, suffer from the disadvantage that playback environments cause considerable distortion and errors in sound reproduction. For example, to those trainees using such systems, the reproduced respiratory sounds do not “sound” as if they are being generated by a live patient. Moreover, the aforementioned playback distortions often make it difficult for the listener to hear and interpret the subtleties of a recorded respiratory maneuver.

This device includes a software program that allows a user to select prerecorded sounds for playback. The program will also generate an inverse model of the playback system in the form of a digital filter. The inverse model processes a selected sound to cancel the distortions of the playback system so the sound is accurately reproduced. The program also permits the extraction of a specific sound component from a prerecorded sound so only the extracted sound component is audible during playback. In addition to the obvious role of a teaching tool for medical professionals, this invention could have applications as a diagnostic screening and/or telemedicine tool.

Potential Commercial Applications:

- Auscultatory training for health care professionals
- Telemedicine tool
- Diagnostic screening comparison and control

Competitive Advantages:

- Accurate, realistic reproduction of in situ physiological sounds

- Apparatus features noise-cancelling filter to eliminate ambient distortion

artifacts during playback

- Device is extremely portable
- Allows for isolation and playback of specific elements of a recording

Development Stage:

- In situ data available (on-site)
- Prototype

Inventors: Walter G. McKinney, Jeff S. Reynolds, Kimberly A. Friend, William T. Goldsmith, David G. Frazer (all of CDC)

Publications:

1. Goldsmith WT, et al. A system for recording high fidelity cough sound and airflow characteristics. Ann Biomed Eng. 2010 Feb;38(2):469-77. [PMID 19876736]
2. Abaza AA, et al. Classification of voluntary cough sound and airflow patterns for detecting abnormal pulmonary function. Cough. 2009 Nov 20;5:8. [PMID 19930559]

Intellectual Property: HHS Reference No. E-283-2013/0 –

- US Patent No. 7,209,796 issued 24 Apr 2007
- International patent application pending (Canada)

Related Technology: HHS Reference No. E-245-2013/0

Licensing Contact: Whitney Blair, J.D., M.P.H.; 301-435-4937;

whitney.blair@nih.gov

Enterovirus Molecular Diagnostic Test Kit

Description of Technology: CDC researchers have developed a reverse transcription/semi-nested polymerase chain reaction (RT-snPCR) assay for diagnosis of enterovirus infections within clinical specimens. Clinical laboratories currently identify enteroviruses by virus isolation and subsequent virus neutralization tests, or serological assays. In addition to being time consuming, these approaches are labor, cost and material intensive.

The enterovirus molecular diagnostic test is prepared in a kit form, consisting of three reagent preparations (three separate test steps), to which a technician adds enzymes and RNA extracted from a clinical specimen. This format is amenable to commercial manufacturing processes. The assay primers were designed for broad specificity and amplify all recognized enterovirus serotypes. In the course of assay development, PCR products have been successfully amplified and sequenced from cerebrospinal fluid, nasopharyngeal swabs, eye swabs, rectal swabs and stool suspensions, allowing for unambiguous identification of the infecting virus in all cases. This assay will be useful for the diagnosis of numerous common illnesses, such as foot-and-mouth disease, respiratory illness, conjunctivitis, neonatal illness, and myocarditis, among several others.

Potential Commercial Applications:

- Detection and identification of enterovirus infections, such as foot-and-mouth disease
- Diagnostic evaluations of respiratory or neonatal illnesses
- Enterovirus surveillance programs for humans and animals/livestock

Competitive Advantages:

- Ready for commercialization

- Easily adaptable to kit form
- Rapid, cost-efficient serotype identification
- High specificity and precision
- Assay covers all known human enterovirus serotypes

Development Stage: In vitro data available

Inventors: William A. Nix and M. Steven Oberste (CDC)

Publications:

1. Nix WA, et al. Sensitive, seminested PCR amplification of VP1 sequences for direct identification of all enterovirus serotypes from original clinical specimens. J Clin Microbiol. 2006 Aug;44(8):2698-704. [PMID 16891480]

2. Nix WA, et al. Identification of enteroviruses in naturally infected captive primates. J Clin Microbiol. 2008 Sep;46(9):2874-8. [PMID 18596147]

Intellectual Property: HHS Reference No. E-257-2013/0 –

- US Patent No. 7,247,457 issued 24 Jul 2007
- US Patent No. 7,714,122 issued 11 May 2010
- Various international patents issued or pending

Licensing Contact: Whitney Blair, J.D., M.P.H.; 301-435-4937;

whitney.blair@nih.gov

Generation of Artificial Mutation Controls for Diagnostic Testing

Description of Technology: This technology relates to a method of generating artificial compositions that can be used as positive controls in a genetic testing assay, such as a diagnostic assay for a particular genetic disease. Such controls can be used to

confirm the presence or absence of a particular genetic mutation. The lack of easily accessible, validated mutant controls has proven to be a major obstacle to the advancement of clinical molecular genetic testing, validation, quality control (QC), quality assurance (QA), and required proficiency testing. This method provides a consistent and renewable source of positive control material, as well as an alternative to patient-derived mutation-positive samples.

Potential Commercial Applications: Generation of positive controls for molecular genetic tests, particularly for tests to detect cystic fibrosis

Competitive Advantages:

- Positive controls can be included in new kits or packaged with pre-existing assays
- Increased accuracy in diagnosis compared to current controls
- Consistent and renewable source for high-quality controls containing mutations of interest

Development Stage:

- Early-stage
- In vitro data available

Inventors: Wayne W. Grody (Regents of Univ of CA), Michael R. Jarvis (Regents of Univ of CA), Ramaswamy K. Iyer (Regents of Univ of CA), Laurina O. Williams (CDC)

Intellectual Property: HHS Reference No. E-255-2013/0 –

- US Patent No. 8,603,745 issued 10 Dec 2013
- Various international patent applications pending or issued

Licensing Contact: Whitney Blair, J.D., M.P.H.; 301-435-4937;

whitney.blair@nih.gov

Novel In Vitro Granuloma Model for Studying Tuberculosis and Drug Efficacy

Description of Technology: CDC researchers have developed an *in vitro* model system designed to simulate early-stage *Mycobacterium tuberculosis* infection and induced granuloma formation. This modeling platform can be used for studying tuberculosis pathogenicity, identifying phenotypically-interesting clinical isolates, studying early-stage host cytokine/chemokine responses, and *in vitro* candidate-drug screening. The approach incorporates autologous human macrophages, human peripheral blood mononuclear cells, and mycobacteria to mimic *in situ* granuloma formation in a controllable *in vitro* environment. This technology would be broadly useful for investigations into the numerous facets of early granuloma host-pathogen interaction, ultimately leading to improved prevention, intervention, and treatment strategies.

Potential Commercial Applications:

- In vitro modeling system
- Basic research into tuberculosis-host interactions
- Drug candidate screening

Competitive Advantages:

- Low-cost alternative for modeling mycobacterial infections within complex tissue systems
- Allows researchers to examine early-stage granuloma formation in a highly controllable, human-based modeling system

- Cost-effective screening of potential therapeutic compounds and/or

phenotypically-interesting mycobacteria

Development Stage:

- In vitro data available
- Prototype

Inventors: Frederick D. Quinn, et al. (CDC)

Publication: Birkness KA, et al. An in vitro model of the leukocyte interactions associated with granuloma formation in Mycobacterium tuberculosis infection. Immunol Cell Biol. 2007 Feb-Mar;85(2):160-8. [PMID 17199112]

Intellectual Property: HHS Reference Nos. E-249-2013/0 and E-249-2013/2 –

- PCT Application No. PCT/US2002/000309 filed on 07 Jan 2002, which published as WO 2002/054073 on 11 Jul 2002 (claiming priority to 08 Jan 2001)
- US Patent No. 7,105,170 issued 12 Sep 2006
- Various international patents issued or pending

Licensing Contact: Whitney Blair, J.D., M.P.H.; 301-435-4937;

whitney.blair@nih.gov

Diagnostic Antigens for the Identification of Latent Tuberculosis Infection

Description of Technology: CDC researchers have developed technology for sero-diagnosis of typically symptomless latent stage tuberculosis disease, posing a threat to individuals under immunosuppressive or anti-inflammatory therapies. Specifically, this diagnostic approach exploits *M. tuberculosis* secreted latency specific antigens, such as alpha-crystallin, in the blood or urine of patients. This type of test could easily be

developed into an inexpensive dip-stick format with high specificity (no cross-reactivity with other mycobacteria), rapidity, and sensitivity (fewer bacteria needed for a positive identification). Because secreted antigens are recognized more readily by the immune system, serum-derived antibodies to these antigens can correspondingly be used for diagnostic or research use.

Potential Commercial Applications:

- Development of a latent tuberculosis diagnostic
- Improvements to current diagnostics
- Public health/tuberculosis monitoring programs
- Screening elderly patients before beginning anti-inflammatory and/or anti-arthritis therapy

Competitive Advantages:

- Rapid and inexpensive diagnostic for latent stage tuberculosis
- Specific for latent form, unlike current IGRA/TST diagnostics
- Easily developed as a cost effective dip-stick test
- Provides high specificity (no cross-reactivity with other mycobacteria) and sensitivity (fewer bacteria needed for a positive identification)

Development Stage:

- In vitro data available
- In vivo data available (human)

Inventors: Frederick D. Quinn, et al. (CDC)

Publication: Stewart JN, et al. Increased pathology in lungs of mice after infection with an alpha-crystallin mutant of *Mycobacterium tuberculosis*: changes in

cathepsin proteases and certain cytokines. Microbiology. 2006 Jan;152(Pt 1):233-44.

[PMID 16385133]

Intellectual Property: HHS Reference Nos. E-249-2013/1 and E-249-2013/2 –

- PCT Application No. PCT/US2002/000309 filed on 07 Jan 2002, which published as WO 2002/054073 on 11 Jul 2002 (claiming priority to 08 Jan 2001)

- US Patent No. 7,105,170 issued 12 Sep 2006

- Various international patents issued or pending

Licensing Contact: Whitney Blair, J.D., M.P.H.; 301-435-4937;

whitney.blair@nih.gov

Methods and Apparatus for Computer-Aided Cough Sound Analysis

Description of Technology: CDC researchers have developed a system that allows subjects to cough into a tubing system allowing the acoustics generated to be recorded with high fidelity and generated data is transferred to a computer for subsequent analysis. Lung diseases can be differentiated by the location of effect in the lungs that produce variations in cough sounds and patterns. Based on these differences, analysis software estimates the lung disease type of the subject. Those who benefit from cough sound analysis include subjects in the early stages of undetected lung disease, subjects with conditions not easily diagnosed by standard techniques, subjects who demonstrate difficulty performing forced expiratory maneuvers and other pulmonary function tests (e.g., elderly, young and very sick patients), and workers whose respiratory functioning may change during the workday.

Potential Commercial Applications:

- Clinical screening for early-stage respiratory illnesses
- Occupational health and safety
- Physiological data collection and algorithmic analysis
- Preventative and early intervention health care

Competitive Advantages:

- Increased accuracy in recorded observations
- Improved objectivity in analysis compared to traditional auscultatory methods
- Broadens the diagnostic toolset of primary/initial care physicians and respiratory

therapists

- Portable for field studies and on-site screening/ diagnostic uses

Development Stage:

- In situ data available (on-site)
- Prototype

Inventors: William T. Goldsmith, David Frazer, Jeffrey Reynolds, Aliakbar Afshari, Kimberly Friend, Walter McKinney (all of CDC)

Publications:

1. Wysong P. Ever Wonder What a Cough Looks Like? The Medical Post 1998;34(21):14. (Third-party Magazine Article about this technology)
2. Abaza AA, et al. Classification of voluntary cough sound and airflow patterns for detecting abnormal pulmonary function. Cough. 2009 Nov 20;5:8. [PMID 19930559]
3. Goldsmith WT, et al. A system for recording high fidelity cough sound and airflow characteristics. Ann Biomed Eng. 2010 Feb;38(2):469-77. [PMID 19876736]

Intellectual Property: HHS Reference No. E-245-2013/0 –

- US Patent No. 6,436,057 issued 20 Aug 2002

- Canada Patent 2,269,992 issued 22 Dec 2009

Related Technology: HHS Reference No. E-283-2013/0

Licensing Contact: Whitney Blair, J.D., M.P.H.; 301-435-4937;

whitney.blair@nih.gov

Methods of Retaining Methylation Pattern Information in Globally Amplified DNA

Description of Technology: CDC researchers have developed a novel method that generates globally amplified DNA copies retaining parental methylation information; making accurate DNA-archiving for methylation studies much more feasible and cost-effective than undertaking such an endeavor with alternate technologies. This unique approach eliminates a significant bottleneck in the collection of methylation information in the genome(s) of an individual organism, hosts and pathogens. Thus, this technology provides numerous opportunities for investigations into cytosine methylation patterns, ultimately benefiting efforts of early detection, control and prevention of many chronic and infectious diseases.

Potential Commercial Applications:

- Epigenetics investigators and related products manufacturers
- Studies into pathogenesis regulation, chronic diseases, gene silencing, etc.
- Cancer and obesity research
- Basic research applications

Competitive Advantages:

- Overcomes a significant barrier inhibiting efficient DNA methylation archival studies

- Substantially reduces the required quantity of sample DNA

- Developed kits will be universally applicable to all species using DNA methylation as regulatory mechanisms of growth, development and/or pathogenesis

- Usable in all situations of limited amounts of DNA, including studies with single cells

- Improved cost effectiveness and study feasibility compared to alternate technologies

Development Stage: In vitro data available

Inventors: Mangalathu Rajeevan and Elizabeth R. Unger (CDC)

Publication: Rajeevan MS, et al. Quantitation of site-specific HPV 16 DNA methylation by pyrosequencing. J Virol Methods. 2006 Dec;138(1-2):170-6. [PMID 17045346]

Intellectual Property: HHS Reference No. E-243-2013/0 – US Patent No. 7,820,385 issued 26 Oct 2010

Licensing Contact: Whitney Blair, J.D., M.P.H.; 301-435-4937;
whitney.blair@nih.gov

Inexpensive, Personal Dust Detector Tube/Dosimeter Operating on a Gas Detector Tube Platform

Description of Technology: This CDC developed dust detector tube is designed to provide inexpensive, short-term, time weighted average dust exposure data feedback

directly to device users. This invention operates upon a conventional gas detector tube platform and can be used with any low volume pump that can electronically measure pump back pressure. The device consists of three sections: the first defines the size of the dust and removes moisture, the second uses a filter whose pressure differential corresponds with cumulative dust loading, and a final section employs a pressure transducer.

Current methods require expensive instantaneous and short-term monitors or gravimetric filters that must be carefully pre- and post-weighed to determine the average dust exposure of a user's work-shift. This novel dust dosimeter fills the need for an inexpensive short-term determination of personal dust exposure aiding in the assessment and preservation of worker respiratory health.

Potential Commercial Applications:

- Dust, gas and particulate detector/dosimeter manufacturers
- Industry applications where worker-exposure to dust will be a concern, especially mining, construction and demolition fields
- Worker health and safety, related insurance agency concerns

Competitive Advantages:

- Provides inexpensive, short-term assessment of personal dust exposure
- Gas detector tube platform makes commercialization of this instrument quite simple and efficient for related manufacturers/distributors
- Standardizing detection platforms increases cost-efficiency (especially for smaller companies) as the same pump can be used to measure both dust and gas

Development Stage: In situ data available (on-site)

Inventors: Jon Volkwein, Harry Dobroski, Steven Page (all of CDC)

Publication: Volkwein JC, et al. Laboratory evaluation of pressure differential-based respirable dust detector tube. Appl Occup Environ Hyg. 2000 Jan;15(1):158-64. [PMID 10712071]

Intellectual Property: HHS Reference No. E-238-2013/0 – US Patent No. 6,401,520 issued 11 Jun 2002

Licensing Contact: Whitney Blair, J.D., M.P.H.; 301-435-4937;
whitney.blair@nih.gov

Peptide Sequences for *Chlamydomophila pneumoniae* Vaccine and Serological

Diagnosis

Description of Technology: CDC researchers have isolated select *Chlamydomophila pneumoniae* peptide epitopes for development of vaccines and diagnostic assays. Currently, *C. pneumoniae* infection of humans has been linked to a wide variety of acute and chronic diseases, such as asthma, endocarditis, atherosclerotic vascular disease, chronic obstructive pulmonary disease, sarcoidosis, reactive arthritis and multiple sclerosis. There is presently no available peptide vaccine for the pathogen and reliable and accurate diagnostic methods are limited.

This technology encompasses polypeptide sequences that are specifically recognized by anti-*C. pneumoniae* antibodies. These antigens may be useful for improving diagnostic methods by reducing the variability and high backgrounds found with methods that rely on whole organisms for detection. Further, this technology may

also be useful for production of peptide or DNA-based vaccines directed against *C. pneumoniae*.

Potential Commercial Applications:

- *C. pneumoniae* vaccine and/or therapeutic developments
- Public health surveillance programs
- Clinical serological diagnostics development

Competitive Advantages:

- No peptide vaccine for *C. pneumoniae* is presently available
- Present assays for the diagnosis of *C. pneumoniae* infections are laborious and limited in efficacy

Development Stage: In vitro data available

Inventors: Eric L. Marston, Jacquelyn S. Sampson, George M. Carlone, Edwin W. Ades (all of CDC)

Publication: Marston EL, et al. Newly characterized species-specific immunogenic *Chlamydomydia pneumoniae* peptide reactive with murine monoclonal and human serum antibodies. Clin Diagn Lab Immunol. 2002 Mar;9(2):446-52. [PMID 11874892]

Intellectual Property: HHS Reference No. E-235-2013/0 – US Patent No. 7,223,836 issued 29 May 2007

Licensing Contact: Whitney Blair, J.D., M.P.H.; 301-435-4937;
whitney.blair@nih.gov

CD40 Ligand: Adjuvant for Enhanced Immune Response to Respiratory Syncytial Virus

Description of Technology: CDC researchers have developed methods and adjuvants for enhancing a subject's immune response to respiratory syncytial virus (RSV) by inclusion of a CD40 binding protein. RSV has long been recognized as a major respiratory tract pathogen of infants, as well as older children and the elderly. Established, successful methods for preventing RSV are currently unavailable. CD40 ligand (CD40L, also known as CD154) is an important costimulatory molecule found on the T-cell and is critical for the development of immunity. CD40L may provide a novel adjuvant to enhance cytokine and antibody response to RSV, directing a subject's immune response further towards Th1-mediated outcomes rather than a less effective Th2-type response. This Th2-type response has been previously suggested as the cause of previous live-RSV vaccine failures. This technology, appropriately developed and integrated into an RSV vaccination agenda, may be useful in improving the efficacy of current or future RSV vaccines.

Potential Commercial Applications:

- Improvements to current RSV vaccines
- Public health vaccination programs
- Enhancing antibody response and T-cell costimulation for targeted immunogenic outcomes
- Pharma development programs focusing on care for neonates, children and the elderly

Competitive Advantages:

- Increased expression of Th1-type cytokines and antibody production
- Enhanced CD40 costimulation
- May overcome prior live-RSV vaccine issues (which generated a primarily Th2-type immune response) by steering post-vaccination immunity further towards a preferred Th1-type (IL-2 and IFN-gamma) response, enhancing virus clearance in vivo

Development Stage:

- In vitro data available
- In vivo data available (animal)

Inventors: Ralph A. Tripp, Larry J. Anderson, Michael P. Brown (all of CDC)

Publication: Tripp RA, et al. CD40 ligand (CD154) enhances the Th1 and antibody responses to respiratory syncytial virus in the BALB/c mouse. J Immunol. 2000 Jun 1;164(11):5913-21. [PMID 10820273]

Intellectual Property: HHS Reference No. E-233-2013/0 –

- PCT Application No. PCT/US2001/003584 filed 02 Feb 2001, which published as WO 2001/056602 on 09 Aug 2001

- US Patent No. 7,371,392 issued 13 May 2008
- US Patent No. 8,354,115 issued 15 Jan 2013
- Various international patents issued

Licensing Contact: Whitney Blair, J.D., M.P.H.; 301-435-4937;

whitney.blair@nih.gov

Recombinant Polypeptides for Clinical Detection of *Taenia solium* and Diagnosis of Cysticercosis

Description of Technology: CDC scientists have developed

synthetic/recombinant polypeptides that can be used for the creation of inexpensive, high-quality cysticercosis diagnostic assays. *Taenia solium* is a species of pathogenic tapeworm. Intestinal infection with this parasite is referred to as taeniasis and it is acquired by ingestion of *T. solium* cysticerci found in raw and undercooked pork, or food contaminated with human or porcine excrement. Many infections are asymptomatic, but infection may be characterized by insomnia, anorexia, abdominal pain and weight loss. Cysticercosis is the formation of cysticerci in various body tissues resulting from the migration of the *T. solium* larvae out of the intestine. Although infection with *T. solium* is itself not dangerous, cysticercosis can be fatal. In the present invention, specific antigen encoding nucleotide sequences have been cloned; assays based on the produced antigens may be useful for improvements over the existing Western blot diagnostic method for identifying individuals with cysticercosis. Additionally, these polypeptides may have applications in developing vaccines and therapeutics to prevent taeniasis.

Potential Commercial Applications:

- Diagnosis of *T. solium* infection and confirmation of cysticercosis
- Zoonotic disease research and surveillance
- Public health monitoring programs
- Livestock health and food-source monitoring
- Therapeutics/vaccine development

Competitive Advantages:

- May provide a rapid, accurate, sensitive and safe alternative to current radiologic, Western blot and biopsy diagnostic methods

- Can be easily formatted as a simple-to-use assay kit for FAST-ELISA
- Cost-effective, and quite useful for developing regions of the world

Development Stage: In vitro data available

Inventors: Victor C. Tsang, Ryan M. Greene, Patricia P. Wilkins, Kathy

Hancock (all of CDC)

Publication: Greene RM, et al. Taenia solium: molecular cloning and serologic evaluation of 14- and 18-kDa related, diagnostic antigens. J Parasitol. 2000 Oct;86(5):1001-7. [PMID 11128471]

Intellectual Property: HHS Reference No. E-230-2013/0 –

- PCT Application No. PCT/US2001/003584 filed 02 Feb 2001, which published as WO 2001/075448 on 11 Oct 2011

- US Patent No. 7,094,576 issued 22 Aug 2006

- US Patent No. 7,595,059 issued 29 Sep 2009

Licensing Contact: Whitney Blair, J.D., M.P.H.; 301-435-4937;

whitney.blair@nih.gov

Automated Microscopic Image Acquisition, Compositing and Display Software

Developed for Applied Microscopy/Cytology Training and Analysis

Description of Technology: Micro-Screen is a CDC developed software program designed to capture images and archive and display a compiled image(s) from a portion of a microscope slide in real time. This program allows for the re-creation of larger images that are constructed from individual microscopic fields captured in up to five focal planes and two magnifications. This program may be especially useful for the

creation of data archives for diagnostic and teaching purposes and for tracking histological changes during disease progression.

Potential Commercial Applications:

- Medical/cytology training, education and certification
- All aspects of applied microscopy/histology, microbial smears, hematology, parasitology, etc.

- Clinical diagnostics
- Basic and applied biology lab research
- Forensic analysis

Competitive Advantages:

- Readily adaptable to other microscopic disciplines
- Automated imaging and display provides increased cost efficiency and improves objectivity of analysis and testing
- Can be used to develop a database of standards or reference images for a variety of pathologies and/or applied microscopy concerns

Development Stage:

- In vitro data available
- In situ data available (on-site)

Inventors: MariBeth Gagnon, Roger Taylor, James V. Lange, Tommy Lee, Carlyn Collins, Richard Draut, Edward Kujawski (all of CDC)

Publication: Taylor RN, et al. CytoView. A prototype computer image-based Papanicolaou smear proficiency test. Acta Cytol. 1999 Nov-Dec;43(6):1045-51. [PMID 10578977]

Intellectual Property: HHS Reference No. E-228-2013/0 –

- US Patent No. 7,027,628 issued 11 Apr 2006
- US Patent No. 7,305,109 issued 04 Dec 2007

Licensing Contact: Whitney Blair, J.D., M.P.H.; 301-435-4937;

whitney.blair@nih.gov

Ultrasonic in situ Respirator Seal-Leakage Detection with Real-time Feedback Capabilities

Description of Technology: This CDC invention entails methods and apparatuses for *in situ* testing seal integrity and improved operation of respiratory masks (respirators). A variety of external factors, such as individual face shape, user environment, mask age and material used to construct the respirator, can lead to device malfunction and failure to sufficiently protect a user. To address these limitations, this invention relies on ultrasonic wave detection to assess face seal quality and other potential leak paths, as needed. Airborne ultrasound travel through atmosphere and will travel through respirator leaks. Applying this phenomena to occupational health and safety, CDC researchers have developed novel ultrasonics technology to identify and quantify respirator seal leakage in real-time. Small, low power consuming, and inexpensive apparatuses and methods for generating and detecting ultrasound may be easily obtained and customized for a given respirator and/or application.

By correlating user activity to seal sensor data, a precise understanding and awareness of respirator integrity may be obtained. When coupled with a subject alarm, these integrated values can immediately alert a user when a threshold of environmental

exposure has been reached. Such real-time feedback will be invaluable to users in dangerous occupational activities, such as firefighters, biodefense and chemical spill first responders, mining applications, etc. Additionally, this invention possesses immense value for respirator mask manufacturers and workplace training programs for employees engaged in mandatory respirator usage applications.

Potential Commercial Applications:

- Manufacturers of respirators, leakage assessment devices and applied ultrasonic technology

- Regulators of respiratory protection plans

- Biohazard, biodefense and hazardous chemical handling and disposal

- Surgery/hospital training and use

Competitive Advantages:

- Small, low power consuming, and inexpensive apparatuses and methods may be employed

- Real-time monitoring and feedback greatly diminish risk of user exposure to environmental hazards

Development Stage:

- In situ data available (on-site)

- Prototype

Inventors: Jonathan Szalajda and William King (CDC)

Intellectual Property: HHS Reference No. E-174-2013/0 – US Patent No.

8,573,199 issued 05 Nov 2013

Licensing Contact: Whitney Blair, J.D., M.P.H.; 301-435-4937;

whitney.blair@nih.gov

Physiologic Sampling Pump Capable of Rapidly Adapting to User Breathing Rate

Description of Technology: This CDC developed physiologic sampling pump (PSP) overcomes shortcomings of previous devices by the use of calibrated valves in conjunction with a constant speed pump. This novel approach obviates typical PSP inertia that inherently limits system response, functionality and accuracy. All prior PSP designs have attempted to follow a user's breathing pattern by changing pump speed, thereby altering sampling rate. In that approach, pump inertia will limit system response and function due to the time required to adjust speed. Additionally, variable pump speeds often produce size selective sampling errors at low flow rates.

Performance of this PSP is not degraded by pump inertia or low flow size selective sampling errors. This design maintains a consistent pump speed, controlling PSP sampling rate with calibrated valves that redirect air flow almost instantaneously. In situ device testing demonstrated that when this air-flow valve is properly integrated into a sampling head, response time of the PSP is essentially mutually exclusive of the magnitude of changes in the effective flow, facilitating consistently small error in sampling performance regardless of user-exertion scenario.

Potential Commercial Applications:

- Air sampling device manufacturers
- Assessing airborne hazard exposures for workplace safety
- Industrial hygiene programs

- Respiration monitoring device for patients
- Aerobic training system for athletes

Competitive Advantages:

- Allows for air sampling to be modulated to follow breathing rate
- Design obviates the sluggishness inherent in prior art physiologic sampling pumps (PSPs) caused by variable pump speed effect on sampling rate
- Improved accuracy compared to earlier PSPs, irrelevant of user-exertion scenarios
- Follows inhalation on a breath-by-breath basis

Development Stage:

- In situ data available (on-site)
- Prototype

Inventors: Larry Lee and Michael Flemmer (CDC)

Publication: Lee L, et al. A novel physiologic sampling pump capable of rapid response to breathing. J Environ Monit. 2009 May;11(5):1020-7. [PMID 19436860]

Intellectual Property: HHS Reference No. E-169-2013/0 – US Patent No. 8,459,098 issued 11 Jun 2013

Licensing Contact: Whitney Blair, J.D., M.P.H.; 301-435-4937;
whitney.blair@nih.gov

Cylindrical Handle Dynamometer for Improved Grip-Strength Measurement

Description of Technology: CDC researchers have developed an improved dynamometer device and method for measuring maximum hand grip force or grip-

strength. Human test subjects were used in conducting experiments to evaluate the handle and to assess the measurement method. In contrast to the currently used "Jamar handle" grip strength dynamometer devices, the cylindrical handle proved to be able to determine the overall grip strength for a subject, as well as show the grip force distribution around the circumference of the handle. The cylindrical dynamometer handle is accurate with less than 4% error, and it demonstrates that the measurement is independent of the loading position along the handle. For real-world applications, the device can be used to help diagnose the musculoskeletal disorders of the hand, monitor the recovery progress after hand surgery or injury, and collect grip strength data for tool and machine design.

Potential Commercial Applications:

- Useful for engineering functional design and ergonomic considerations for developing new tools and machinery
- Monitoring post-operative, post-stroke rehabilitation
- Diagnosis of carpal tunnel syndrome, musculoskeletal disorders and hand-arm vibration syndrome
- Training feedback for grip-strength focused athletes - climbing, gymnastics, rugby, martial arts, etc.

Competitive Advantages: Compared to currently used "Jamar" grip test devices:

- Cylindrical handle shape more comparable with real-world/workplace machinery
- Improved comfort

- Cylindrical meter assesses the total grip force, together with the friction force and torque

- Grip force distributed at the different parts of the hand can be measured with cylindrical meter - important information for the diagnosis of hand disorders

Development Stage:

- In situ data available (on-site)
- Prototype

Inventors: Bryan Wimer, Daniel E. Welcome, Christopher Warren, Thomas W. McDowell, Ren G. Dong (all of CDC)

Publication: Wimer B, et al. Development of a new dynamometer for measuring grip strength applied on a cylindrical handle. Med Eng Phys. 2009 Jul;31(6):695-704.

[PMID 19250853]

Intellectual Property: HHS Reference No. E-143-2013/0 – US Patent No. 8,240,202 issued 14 Aug 2012

Licensing Contact: Whitney Blair, J.D., M.P.H.; 301-435-4937;
whitney.blair@nih.gov

Methods for the Simultaneous Detection of Multiple Analytes

Description of Technology: CDC researchers have developed a method of simultaneously detecting and distinguishing multiple antigens within a biological sample. Epidemiological and vaccine studies require species serotype identification. Current methods of serotyping are labor intensive and can easily give subjective, errant results. This technology utilizes serotype specific antibodies bound to fluorescent beads, allowing

for simultaneous single tube capture and detection of multiple antigens in one rapid, high-throughput flow cytometry assay. Such technology has an extremely wide range of useful applications, including but not limited to complex serotyping investigations for vaccine development and formulation, as a tool for rapid clinical prognosis or diagnosis, and the assay can be formatted as a kit for any number of laboratory research uses.

Potential Commercial Applications:

- Complex serotyping and/or multi-antigen composition investigations
- Tool for clinical diagnosis or prognosis of a disease or infection
- Tool for basic research

Competitive Advantages:

- Rapid flow cytometry assay
- Simultaneous detection of multiple different antigens and antibodies
- Excellent for high-throughput usage
- Provides a reliable, reproducible measurements of serotype-specific antigens

within a sample

- Technology particularly well-developed for addressing *S. pneumoniae*

serotyping concerns

Development Stage: In vitro data available

Inventors: Joseph E. Martinez and George M. Carlone (CDC)

Intellectual Property: HHS Reference No. E-142-2013/0 – US Patent No.

7,659,085 issued 09 Feb 2010

Licensing Contact: Whitney Blair, J.D., M.P.H.; 301-435-4937;

whitney.blair@nih.gov

Extension-Ladder Safety: Multimodal-feedback Indicator for Improved Ladder Positioning Safety and Efficiency

Description of Technology: Improper positioning of an extension ladder frequently results in "ladder slide-outs," which are the most common cause of ladder-fall scenarios. This invention relates to an extension ladder positioning indicator which is easily installed in a ladder rung; provides multiple cues (visual, sound, and vibration) for rapidly identifying and positioning correct ladder inclination.

CDC-NIOSH researchers found that this technology improved accuracy and efficiency of ladder positioning for both "experienced" and "novice" ladder users, as compared to the "no instruction" method and the standard anthropometric method, and that it was also significantly faster than the bubble indicator method. When properly implemented, this effective and easy to use ladder positioning indicator will reduce the risk of extension ladder slipping and tipping and, ultimately, will reduce the number of fall incidents and injuries – benefitting construction workers, employers, contractors and workplace insurers.

Potential Commercial Applications:

- Retrofitting existing ladders to provide automated, multisensory feedback for improved compliance with OSHA and ANSI ladder-angle safety guidelines
- Ladder manufacturing companies
- Construction contractors, retailers and insurers
- Training tool to aid worker safety education and adherence

Competitive Advantages:

- Direct, multimodal user feedback reduces the time for accurate, safe ladder positioning compared to bubble-level indicator, anthropometric and sight- based ladder-positioning methods
- Visual, auditory and tactile feedback provide increased efficient-setup and safety
- Technology can be incorporated as an attachable, device which may be affixed to a ladder or integrated as an app for a mobile/tablet device
- Automated feedback ensures ladders are angled to OSHA and ANSI safety specifications

Development Stage:

- In situ data available (on-site)
- Prototype

Inventors: Peter Simeonov, Hongwei Hsiao, John Powers (all of CDC)

Publication: Simeonov P, et al. Research to improve extension ladder angular positioning. Appl Ergon. 2013 May;44(3):496-502. [PMID 23177178]

Intellectual Property: HHS Reference No. E-141-2013/0 – US Patent No 8,167,087 issued 01 May 2012

Licensing Contact: Whitney Blair, J.D., M.P.H.; 301-435-4937;
whitney.blair@nih.gov

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Richard U. Rodriguez,
 Director,
 Division of Technology Development and Transfer,
 Office of Technology Transfer,
 National Institutes of Health.

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